# The effects of bisphosphonates on disease activity and bone status in ankylosing spondylitis (BIAS)

	<ul> <li>Prospectively registered</li> </ul>
04/05/2005 No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Musculoskeletal Diseases	<ul><li>Record updated in last year</li></ul>
	Completed  Condition category

## Plain English summary of protocol

Not provided at time of registration

#### Study website

http://www.arc.org.uk/research/grantdet.asp?Code=B0735

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Ashok Bhalla

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

14585

# Study information

#### Scientific Title

#### Acronym

**BIAS** 

## Study objectives

The bisphosphonates will not alter clinical outcome in ankylosing spondylitis

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

## Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Not specified

# Study type(s)

**Not Specified** 

#### Participant information sheet

# Health condition(s) or problem(s) studied

Ankylosing Spondylitis (AS)

#### **Interventions**

Placebo or Alendronate 70 mg weekly

#### Intervention Type

Drug

#### **Phase**

**Not Specified** 

## Drug/device/biological/vaccine name(s)

alendronate

#### Primary outcome measure

**BAS-G** 

#### Secondary outcome measures

BASDAI, BASFI and BASRI, ESR, CRP, use of NSAIDs, bone density and vertebral deformity.

#### Overall study start date

01/08/2004

#### Completion date

31/08/2006

# **Eligibility**

#### Key inclusion criteria

Age > 21, stable dose of non-steroidal anti-inflammatory drug (NSAID) for last four weeks. Need to fulfil New York Criteria for AS.

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Sex

**Not Specified** 

## Target number of participants

180

#### Key exclusion criteria

- 1. Systemic steroids for the last three months
- 2. Bisphosphonates in the last 12 months
- 3. Oesophageal disease or active peptic ulcer
- 4. Unable to give informed consent
- 5. Known Paget's Disease
- 6. Renal disease with creatinine >150 mmol/l, hypercalcaemia, osteomalacia, inflammatory bowel disease, known malignancy and reduced life expectancy <2 years

#### Date of first enrolment

01/08/2004

#### Date of final enrolment

31/08/2006

# Locations

#### Countries of recruitment

England

**United Kingdom** 

Study participating centre Dept of Rheumatology

Bath United Kingdom BA1 1RL

# Sponsor information

#### Organisation

Royal National Hospital for Rheumatic Diseases (UK)

# Sponsor details

Upper Borough Walls Bath United Kingdom BA1 1RL +44 (0)1225 473440 Nicola.Carmichael@rnhrd-tr.swest.nhs.uk

#### Sponsor type

Not defined

#### **ROR**

https://ror.org/05va5gy74

# Funder(s)

# Funder type

Charity

#### **Funder Name**

Arthritis Research Campaign 14585

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration